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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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HM12/0511

EXAMINER

TUNG, J

ART UNIT

PAPER NUMBER

1653

9

DATE MAILED:

05/11/99

PI as find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/076,115

Applicant(s)
Gruber et al

Examiner
Joyce Tung

Group Art Unit
1653



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 2, 6, 12, 16-20, 22, 25, 28, 29, 31-33, 35, 36, 40-45, 49, 51, and 53 are pending in the application.

Of the above, claim(s) 33, 35, 36, 40, 44, 45, 49, 51, and 53 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 6, 12, 16-20, 22, 25, 28, 29, 31, 32, and 41-43 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1, 2, 6, 12, 16-20, 22, 25, 28, 29, 31-33, 35, 36, 40-45, 49, 51, and 53 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 and 8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1, 2, 6, 12, 16-20, 22, 25, 28, 29, 31, 32 and 41-43 in Paper No. 7 is acknowledged.
2. Claims 33, 35, 36, 40, 44-45, 49, 51 and 53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected Group II-VI.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, 6, 12, 16-20, 22, 25, 28, 29 and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Claims 1, 2, 6, 12, 16-20, 22, 25, 28, 29 and 31-32 are vague and indefinite because of the language "under conditions sufficient to" in claims 1 and 29. It is not clear whether the same polymerase or reverse transcriptase as mentioned in claims 1(a) is involved in the condition to

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make a first nucleic acid molecule or there is an additional enzyme used. It is suggested to clarify uncertainty.

b. Claim 6 is vague and indefinite because of the language “variants and derivatives thereof”. It is not clear what is the metes and bounds for the language “variants and derivatives thereof”.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1, 2, 6, 12, 16-20, 22, 25, 28, 29, 31, 32 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burner (5,726,022) in view of Carninci et al. (Genomics, 1996, Vol. 37, pg. 327-336).

Burner discloses a method and kit to isolate nucleic acid sequences. The method involves using an adaptor which includes a restriction site and a ligand binding end ligated to the nucleic acid fragment of a first and second nucleic acid samples to provide the nucleic acid complementary to a primer for amplification (see column 4, lines 16-25). If the fragment of the second nucleic acid samples are amplified, the primers used contain a ligand binding end (see column 4, lines 26-30). The isolation step is done by first removing the adaptors by restriction enzyme, capturing the nucleic acid containing the ligand and then the nucleic acid that were not captured is isolated (see column 2, lines 56-59). The ligand includes hapten (see column 7, line 4). The amplification is done by PCR, LCR and TAS (see column 8, lines 47-52). The solid support is described in column 7, lines 37-48.

Burner does not disclose using a primer which has a restriction enzyme recognition site incorporated into a nucleic acid sequence via amplification.

Carninci et al. disclose a method for efficiently constructing high-content full-length cDNA libraries. The method involves using a primer inserted with restriction sites, the restriction sites are incorporated into cDNA by PCR with ExTaq DNA polymerase and the amplified nucleic acid is cleaved by the restriction enzyme (see pg. 329, column 1-2, the fourth and fifth paragraph).

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The teachings of Burner and Carninci et al. suggest instant claims 1, 2, 6, 12, 16-20, 22, 25, 28, 29, 31, 32 and 41-43 in which the method is used for making or isolating a nucleic acid comprising mixing a DNA template with polymerase and a primer-adaptor nucleic acid molecule containing a ligand and restriction site to produce a first nucleic acid molecule. The polymerase is described in instant claim 6. The method also involves making a second nucleic acid molecule complementary to the first nucleic acid molecule in which the steps are the same as for making the first nucleic acid molecule. The ligand binds to haptens bound to a solid support forming a nucleic acid ligand-hapten complex and the nucleic acid molecule is isolated by cleaving from the complex at the cleavage sites.

One of ordinary skill in the art at the time of the instant invention would have been motivated to combine the references of Burner and Carninci et al. for reasonable expectation of success because Burner indicates that the method provides simple and inexpensive means for isolating a nucleic acid (see column 2, lines 24-25) since the method uses a ligated adaptor containing a restriction site and ligand which allows molecules to be rescued from both the captured population (see column 1, ^{lines 59-64}) and the method also involves a ligand binding primer for amplifying a nucleic acid fragment. The isolation is done by cleaving the restriction site and the nucleic acids which are not captured are isolated. These features of the method simplify the method. Carninci et al. teach using a primer inserted with restriction sites, the restriction sites are incorporated into an amplified nucleic acid via amplification and the amplified nucleic acid can be cleaved by a restriction enzyme. Therefore, an artisan of ordinary skill would have combined

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the references by using a primer containing a restriction site and a ligand, and the restriction site and ligand are incorporated into a target nucleic acid by amplification reaction which have been taught in the reference above for making or isolating a nucleic acid sequence as claimed in instant claims. This would have even further simplified the steps by excluding the ligation step in which the adaptor is ligated to a target nucleic acid as taught by Burmer. An artisan of ordinary skill would have constructed the kit for practicing the method which includes all ingredients because packing all ingredients into a kit for practicing a method was routine in the art at the time of the instant invention. It would have been prima facie obvious to carry out the invention as claimed.

7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bradley Sisson can be reached at (703) 308-3978

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1653 via the PTO Fax Center located in Crystal

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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

May 4, 1999


ARDIN H. MARSCHEL
PRIMARY EXAMINER